K002493

NOV 3 0 2000

510(k) SUMMARY

SUBMITTER: Dideco S.p.A.
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41037 Mirandola (MO) Italy

CONTACT PERSON: Luigi Vecchi
Regulatory Affairs Manager
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APPLICANT: COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, Colorado 80004-3599 USA

CONTACT PERSON: Lynne Leonard
COBE Cardiovascular, Inc.
Sr. Regulatory and Clinical Affairs Manager
Phone: 303-467-6586
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DATE PREPARED: August 2, 2000

DEVICE TRADE NAME: Dideco Micro 40 Ph.I.S.I.O (Phosphorylcholine Inert Surface In Oxygenation) Newborn/Infant Arterial Filter
Product Designation: D736

COMMON NAME: Arterial filter

CLASSIFICATION NAME: Cardiopulmonary Bypass Arterial Filter

PREDICATE DEVICES: Dideco Micro 40 Arterial Filter (K961869)
Dideco Lilliput Ph.I.S.I.O Oxygenator (K991737)

DEVICE DESCRIPTION:

The Dideco Micro 40 Ph.I.S.I.O is an arterial filter with an integral bubble trap and an optional attached purge line. The blood contact surfaces of the device have been coated with a phosphorylcholine coating. The coating provides a uniform biocompatible surface.

INDICATION FOR USE:

The Dideco Micro 40 Ph.I.S.I.O Arterial Filter is intended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass, for periods up to six hours. The filter is used to trap and remove gaseous emboli as well as particulate debris that may be introduced through the arterial line.

TECHNOLOGICAL CHARACTERISTICS:

The Dideco Micro 40 Ph.I.S.I.O Arterial Filter is identical in design to the Dideco Micro Arterial Filter, with the exception that all blood contact surfaces have been coated with a biocompatible phosphorylcholine coating. The coating is identical to the PC coating used on the Dideco Lilliput Ph.I.S.I.O Oxygenator. The Dideco Micro 40 Ph.I.S.I.O Arterial Filter is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:1992 and FDA Blue Book Memorandum G95-1 for biocompatibility testing on the raw materials. The whole coated device accelerated aged to the equivalent of two years was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity, Sensitization and Mutagenicity. Sterility, pyrogenicity, ethylene oxide residuals and package integrity testing were also conducted. The results of this testing met established specifications.

IN VITRO TEST RESULTS:
Product performance testing included blood-side pressure drop, filtration efficiency, hemolysis/cell changes, mechanical integrity, air-handling characteristics (gaseous micro-emboli removal efficiency), flow rate capacity (priming volume), ease of prime characteristics, blood compatibility, and leachables/flaking tests. Many of the test protocols used were based on the FDA draft guidance "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submission" issued on February 21, 2000. All tests were performed upon aged devices (accelerated aged to an equivalent of 2 years); for comparative purposes, the same testing (when applicable) was conducted also on the Micro predicate device.
The results of these tests show that the Dideco Micro 40 Ph.I.S.I.O Arterial Filter is substantially equivalent to the predicate device. The addition of the phosphorylcholine coating creates a more biocompatible surface and enhances the wettability and de-bubbling characteristics of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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COBE Cardiovascular, Inc.
c/o Ms. Lynne Leonard
Senior Regulatory and
Clinical Affairs Manager
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K002493
Dideco Micro 40 Ph. I.S.I.O. Newborn/Infant Arterial Filter
Regulatory Class: III (Three)
Product Code: DTM
Dated: August 2, 2000
Received: August 14, 2000

Dear Ms. Leonard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4686. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002493

Device Name: Dideco Micro 40 Ph.I.S.I.O Newborn/Infant Arterial Filter

Indications For Use:

The Dideco Micro 40 Ph.I.S.I.O Arterial Filter with 40 micron screen is recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass, for periods up to six hours. The filter is used to trap and remove gaseous emboli as well as particulate debris that may be introduced through the arterial line. The filter has a maximum rated blood flow of 2.5 liters/minute.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002493

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)